



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,440	11/26/2001	Melissa K. Carpenter	091/010C	1921
22869	7590	07/27/2004	EXAMINER WOITACH, JOSEPH T	
GERON CORPORATION 230 CONSTITUTION DRIVE MENLO PARK, CA 94025			ART UNIT 1632	PAPER NUMBER

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

84-

Office Action Summary**Application No.**

09/994,440

Applicant(s)

CARPENTER ET AL.

Examiner

Joseph T. Voitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1632

DETAILED ACTION

Please note that the Examiner of record and art unit has changed. The Examiner of record is now **Joseph T. Voitach** and the group art unit is now **1632**.

This application is a continuation of 09/859,291 filed May 16, 2001, which claims benefit to provisional applications: 60/175,581, filed January 11, 2000; 60/213,740, filed June 22, 2000; 60/213,739, filed June 22, 2000; 60/216,387, filed July 7, 2000; and 60/220,064, filed July 21, 2000.

Applicants' amendment filed May 16, 2004 has been received and entered. The specification has been amended. Claims 1 and 2 have been amended. Claims 1-15 are pending and currently under examination.

Specification

The amendment filed May 14, 2004, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The amendment which indicates particular culturing conditions and suggests synthetic and beneficial conditions derived from embryonic fibroblasts is new matter because the amendment was not present and thus, not part of the original disclosure. There is no specific disclosure of what the soluble factors are or specifically how conditioned media is made using

Art Unit: 1632

embryonic fibroblasts to determine how to make a synthetic mixture that would be beneficial.

Therefore, the attempt to incorporate the information as recited by the new amendment is considered new matter because this was not part of the original disclosure. See MPEP 608.04.

Applicant is required to cancel the new matter in the reply to this Office Action.

In addition, the disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (for example: page 3, line 21 and page 28, line 22). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required.

Applicants have claimed priority to provisional application 60/175,581 filed January 11, 2000, however this is more than a year before the filing date of 09/859,291, filed May 16, 2001. The provisional application became abandoned one year after the filing date, therefore was not copending with '291. Accordingly, the earliest effective filing date given the instant application is to 60/213,740, filed June 22, 2000.

Art Unit: 1632

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 7, 8, 10-13 and 15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending Application Nos. 10/330,873, 10/235,094, 09/859,291, 10/087,473.

Applicants indication that the rejection will be addressed once allowable subject matter has been indicated is noted, however the rejection can not be held in abeyance. No other arguments have been presented therefore, the rejections are maintained for the reasons of record. It is noted that this is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1632

Claims 1-15 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn.

The amendment to the claims has obviated the basis of the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendment to claim 2 has obviated the basis of the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson *et al.* (Science 1998 and APMIS 1998-IDS references) and Gearhart *et al.* (US Patent 6,245,566 B1).

The claimed invention encompasses obtaining human embryonic stem cells from the inner cell mass of a blastocyst, culturing said cells free of feeder cells and differentiating the cells into a variety of different cell types including neuronal, fibroblast, hepatic cell types. At the time of the claimed invention, human embryonic stem cells were known (Thomson *et al.*). It was demonstrated that these cells are highly pluripotent and could be maintained in culture for prolonged periods of time without differentiating. Further, it was demonstrated that under proper culturing conditions the cells could be induced to differentiate into specific cell type lineages (Thomson *et al.*). Though Thomson *et al.* provides demonstrates methods and conditions for isolating, culturing and differentiating human embryonic stem cells isolated from a human blastocyst, the references do not provide a general knowledge in the art of other methods known and used to differentiate stem cells in culture. Specifically, Thomson *et al.* does not teach to use feeder cell free conditions and/or culturing the cells on an extracellular matrix for the maintenance of stem cells. At the time of filing Gearhart *et al.* teach culture conditions where human embryonic cells can be cultured in feeder free conditions by culturing them on an extracellular matrix (column 9, lines 57-67). It is noted that Gearhart *et al.* teaches human embryonic germ cells, not embryonic stem cells like Thomson *et al.*, however as taught by both Thomson *et al.* and Gearhart *et al.* these embryonic cells share many of the same properties including being highly pluripotent and capable of differentiating into multiple cell types (also

Art Unit: 1632

acknowledged by the present specification in Background section in the review of the prior art- pages 2-3, and more generally in the description of pluripotent stem cells-pages 3-4 and 8).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use any of the various known conditions of maintaining and differentiating embryonic stem cells such as those taught by Gearhart *et al.* for the culturing of human embryonic stem cells. In this case, one having ordinary skill in the art would have been motivated to substitute feeder free conditions with an extracellular matrix in order to obtain a pure population of stem cells and cultures free from contaminants of feeder cells. Further, the use of feeder free conditions relying only on extracellular matrix provides a more simple, reproducible and controlled culturing condition overcoming the variability of feeder cell batches and avoiding potential contaminants of co-culturing different cell types. The art teaches that both EG and ES cells are phenotypically similar, and the greatest difference between human EG and ES cells is their source. There would have been a reasonable expectation of success given the results of both Thomson *et al.* and Gearhart *et al.* to use the methods taught by Gearhart *et al.* to culture the ES cells taught by Thomson *et al.* given the art recognized similarity of both human EG and ES cells. Moreover, given the art teaches methods of differentiating various pluripotent cells requires the same compliment of factors for obtaining a given committed cell lineage, any method known in the art of differentiating pluripotent cells would make obvious the methodology for use in differentiating human ES cells (for example Thomson *et al.*- APMIS, 1998).

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Art Unit: 1632

Conclusion

No claim is allowed. Applicants' amendments to the claims have obviated the previous rejections of record, however a new rejection with prior art not previously made of record has been made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Voitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach

Joe Voitach
AU1632